

Application Number 10/731,868

Amendment in response to Final Office Action mailed April 17, 2008

REMARKS

This amendment is responsive to the Final Office Action dated April 17, 2008. Applicant has amended claims 1, 7, 11, 25 and 26, canceled claim 8 and added claim 32. Claims 1-7, 9-17 and 24-32 are pending; of these, claims 13 and 14 are currently withdrawn.

Objection to the Specification

The Office Action objected to the amendment filed September 7, 2007 under 35 U.S.C. §132(a) as introducing new matter. Although Applicant does not agree with or acquiesce to this objection, with this Amendment, Applicant has deleted the objected-to portion of the specification for the purpose of advancing prosecution of this application. For this reason, the objection to the specification under 35 U.S.C. §132(a) is now moot. Applicant respectfully requests the Examiner withdraw this objection.

Claim Rejection Under 35 U.S.C. § 112

In the Final Office Action, the Examiner rejected claims 1-12, 15-17, 24-27 and 29-31 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. Applicant respectfully traverses this rejection to the extent that may be considered applicable to the claims as amended.

Placing a majority of the IMD in the pocket

As amended, Applicant's claims no longer recite the feature of "placing a majority of the IMD in the pocket." For this reason, the rejection under 35 U.S.C. §112, first paragraph is now moot to the extent this rejection is based on this a feature. Applicant does not agree with or acquiesce to this rejection, but has amended the claims for the purpose of advancing prosecution of this application

Recess and pocket

With respect to claims 12 and 27, written description of the feature of placing an IMD within a recess is provided by, e.g., paragraph [0051] of Applicant's specification as filed. The Office Action argues that this is an alternative method of implantation. However, the context of

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paragraph [0051] of Applicant's specification as filed provides support for the combination of placing an IMD within a pocket and a recess. As stated in paragraph [0046] of Applicant's specification as filed, "In some cases, implantation of an IMD may include an extra surgical stage." Following a discussion of the use of a dummy IMD in paragraphs [0046]-[0050], paragraph [0051] states in part, "In addition, the surgeon may in some cases determine that the skull of the patient may be prepared to receive the IMD. The surgeon may, for example, create one or more troughs or recesses in the skull of the patient to receive the IMD or one or more modules thereof." (Emphasis added.) Clearly, in this context, Applicant's specification discloses the combination of a recess and a pocket.

Placing all of the IMD in the pocket

With respect to claims 25 and 29, written description of the feature of "placing all of" is provided by, e.g., paragraph [0022] of Applicant's specification as filed, which states, in part, "[t]he pocket may be opened sufficiently to receive IMD 12 or a portion thereof" (emphasis added). This statement illustrates that all or a portion of IMD 12 may be placed in a pocket. Applicant notes that mere rephrasing of a passage does not constitute new matter.¹

The Office Action argued that this passage did not clearly suggest all of the device is inserted into the pocket. However, the term "or" in the phrase "IMD 12 or a portion thereof" (emphasis added) indicates that "a portion thereof" must mean something different than "IMD 12." Logically, since the reference to IMD 12 can not mean only a portion of IMD 12, it must be a reference to all of IMD 12. The clear meaning of this statement is not refuted by any other disclosure in Applicant's specification as filed. For example, the mere fact that Applicant's specification describes alternative embodiments to those which include placing all of an IMD within a pocket is not evidence that Applicant did not have embodiments including the feature of placing all of an IMD within a pocket in Applicant's possession at the time of filing.

¹ *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973) as cited in MPEP 2163.07.

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Conclusion

Each of the claims recites subject matter included in the present application as originally filed. For this reason, Applicant requests immediate withdrawal of each of the rejections under 35 U.S.C. §112.

Claim Rejections Under 35 U.S.C. § 102

The Office Action rejected claims 1-3, 5-10, 12, 15-17, 25-27 and 31 under 35 U.S.C. §102(e) as being anticipated by U.S. Pat. No. 6,648,914 to Berrang et al. (hereinafter "Berrang"). The Office Action also rejected claims 1-4, 7, 15 and 25-27 and 31 under 35 U.S.C. §102(e) as being anticipated by U.S. Pub. No. 2003/0109903 Berrang et al. (hereinafter "Berrang Application"). Applicant respectfully traverses these rejections to the extent that they may be considered applicable to the claims as amended. The applied references fail to disclose each and every feature of the claimed invention, as required by 35 U.S.C. §102(e), and provide no teaching that would have suggested the desirability of modification to include such features.

Claims 1-7, 9, 10, 12, 15-17, 24, 25 and 31

As amended, claim 1 recites drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull; and inserting one or more leads through the burr holes and into a brain of the patient. Prior to this amendment, similar features were recited in claim 8. The amendment to claim 1 is also supported by FIGS. 1-11 and paragraphs [0019]-[0022]. The Office Action cited Berrang column 14, lines 52-59 as disclosing drilling a hole for a lead. However, in contrast to the subject matter of claim 1, Berrang fails to disclose drilling a burr hole in a portion of the skull of the patient exposed by separating the scalp flap from the skull, or placing a lead through the burr hole and into the brain. Berrang Application also fails to disclose such features.

Furthermore, it would not have been obvious to modify the techniques disclosed by Berrang and Berrang Application to include the features of drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, and inserting one or more leads through the one or more burr holes and into the brain. Berrang and

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Berrang Application disclose techniques for a cochlear implant. The drilling disclosed by Berrang is used to implant a microphone in posterior wall of the external auditory canal of a patient.² The cochlear implants disclosed by Berrang and Berrang Application have no use for drilling a burr hole in the skull of a patient, much less for drilling a burr hole in a portion of the skull of the patient exposed by separating a scalp flap from the skull, and inserting a lead through the hole and into the brain.

In addition, claim 1 recites placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. Berrang and Berrang Application fail to disclose a pocket adjacent to the fold and between the scalp and the skull, or placing at least a portion of a low-profile implantable medical device in the pocket as recited by claim 1. In fact, neither Berrang nor Berrang Application demonstrate that there is any separation whatsoever between a scalp and skull behind a fold as recited in claim 1. Applicant notes that neither Berrang nor Berrang Application discusses any such separation. For example, in contrast to claim 1, Berrang illustrates in FIG. 3 that the implant is placed in front the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.³ Berrang teaches raising the postauricular flap, and placing the device beneath the flap, on the "flap" side of the fold. Berrang in no way suggests the additional step, after raising the flap, of creating a pocket adjacent to the fold and between the scalp and the skull. Because Berrang does not disclose creating a pocket, Berrang also does not disclose placing at least a portion of the low-profile implantable medical device in the pocket.

Similarly, Berrang Application also fails to teach or suggest such a feature. For example, as shown in FIG. 3 of Berrang Application, the implant is placed in front the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.⁴

Because Berrang and Berrang Application fail to disclose a pocket, placing at least a portion a low-profile implantable medical device in the pocket, drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, or inserting one or more leads through the one or more burr holes and into the brain as recited by

² Berrang, column 14, lines 52-59.

³ Berrang, column 13, lines 40-53.

⁴ Berrang Application, paragraph [0056].

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claim 1, Berrang and Berrang Application each fail to anticipate the Applicant's invention as recited in claim 1. For at least the same reasons, Berrang and Berrang Application also fail to anticipate the Applicant's invention as recited in dependent claim 2-7, 9, 10, 12, 15-17, 24, 25 and 31. The dependent claims also recite additional features not taught or suggested by Berrang and Berrang Application.

As an example, claim 25 recites placing all of the low-profile implantable medical device in the pocket. In the rejection, the Office Action stated with reference to both Berrang and Berrang Application that "Figure 3 show (sic) an S-shaped incision and a pocket created right of the S-shaped incision, and adjacent a fold, in which all of the implant (as best understood by Applicant's specification) is placed into."⁵ However, Berrang and Berrang Application fail to mention creation of a pocket, much less placing all of an implant within the pocket.

For at least these reasons, the cited references fail to anticipate Applicant's claims 1-7, 9, 10, 12, 15-17, 24, 25 and 31 as required to maintain the rejection under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

Claims 26 and 27

Independent claim 26 recites placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. As discussed with respect to claim 25 above, such a feature is not taught or suggested by either Berrang or Berrang Application.

In addition, as amended, claim 26 also specifies making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient. As acknowledged in the Office Action, such a feature is not disclosed by either Berrang or Berrang Application.⁶

For at least these reasons, both Berrang and Berrang Application fail to anticipate Applicant's invention as recited by claim 26. The cited references fail to anticipate Applicant's claims 26 and 27 as required to maintain the rejection under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

⁵ Office Action dated April 17, 2008, page 8.

⁶ Office Action dated April 17, 2008, pages 8-9.

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Claim Rejection Under 35 U.S.C. § 103

The Office Action rejected claims 11, 24 and 28-29 as being unpatentable over Berrang or Berrang Application. The Office Action also rejected claim 30 as being unpatentable over U.S. Pat. No. 6,648,914 to Fischell et al. (hereinafter "Fischell") in view of Berrang. Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claim 11

As discussed previously in this response, Berrang and Berrang Application individually and collectively fail to disclose or suggest every element of independent claim 1. Fischell provides no teaching that would have overcome the deficiencies of Berrang and Berrang Application with respect to the elements of claim 1. For example, it would not have been obvious to one of ordinary skill in the art from the disclosures of Berrang, Berrang Application and Fischell to create a pocket and place at least a portion a low-profile implantable medical device in the pocket or obvious to drill one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, as recited by independent claim 1. Because claim 11 is dependent on claim 1, the subject matter of claim 11 would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claim 11 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

Claims 24 and 28-29

Independent claim 28 recites making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient. A similar feature is recited by claim 24, which is dependent on claim 1.

The Office Action acknowledges that such a feature is not disclosed by either Berrang or Berrang Application.⁷ The Office Action further states that even though Berrang and Berrang

⁷ Office Action dated April 17, 2008, pages 8-9.

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Application disclose that the preferably located behind the ear (as show in FIG. 3), that it would have been obvious to locate the device on top of the head to improve the aesthetics of the implanted device.⁸

Applicant respectfully disagrees with this reasoning. First, Berrang and Berrang Application disclose that the device is preferably located behind the ear. Additionally, Berrang and Berrang Application provide no suggestion that locating the device elsewhere may improve the aesthetics of the implanted device. Indeed, Applicant does not see how simply relocating the device on the skull of a patient would improve the aesthetics of the implanted device as the implanted device still result in a lump at the new location. Instead, Berrang discloses that in some embodiments, skull bone may be excavated.⁹ For this reason, if one of skill in the art sought to improve the aesthetics of the implanted device as suggested in the Office Action, one of skill in the art would not deviate from the preferred embodiment by relocating the device, but might instead excavate skull bone.

Furthermore, even if Berrang and Berrang Application did suggest relocating the implanted device, the references provide absolutely no suggestion that the device be relocated to the top of a head of a patient. In this manner, the Office Action appears to rely on Applicant's own disclosure as providing the motivation to locate an implanted device on the top of the head of the patient. This constitutes impermissible hindsight.

In addition, Berrang or Berrang Application teach away from the feature of making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient as recited by claim 21. Relocating components of the implanted devices described by Berrang and Berrang to the top of the head of the patient is impractical. For example, the implanted device disclosed by Berrang includes a microphone positioned adjacent an exterior auditory canal. The location of the microphone is integral to the operation of the implanted device.¹⁰ The implanted device disclosed by Berrang also includes an electrode array in one of the cochlea scala.¹¹ Relocating components of the device to the top of the head of a patient as

⁸ Office Action dated April 17, 2008, page 9.

⁹ Berrang, column 10, lines 13-18.

¹⁰ See, e.g., Berrang, column 6, line 47 to column 7, line 10.

¹¹ See, e.g., Berrang, abstract.

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suggested by the Office Action would increase the distance wires would need to be tunneled under the scalp connect the components.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claims 24 and 28-29 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

Claim 30

As discussed previously in this Response, Berrang fails to disclose or suggest every element of independent claim 1. The Fischell provides no teaching that would have overcome the deficiencies of Berrang with respect to the elements of claim 1. For example, it would not have been obvious to one of ordinary skill in the art from the disclosures of Berrang and Fischell to create a pocket adjacent to the fold and between the scalp and skull, and place at least a portion of a low-profile implantable medical device in such a pocket or to drill one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull as recited by independent claim 1. Because claim 30 is dependent on claim 1, the subject matter of claim 30 would also not have been obvious to one of ordinary skill in the art at the time of Applicant's invention.

For at least these reasons, the Office Action fails to establish a prima facie case for non-patentability of Applicant's claim 30 under 35 U.S.C. §103(a). Withdrawal of this rejection is requested.

New Claim

Applicant has added claim 32 to the pending application. The applied references fail to disclose or suggest the inventions defined by Applicant's new claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed inventions. As one example, the references fail to disclose or suggest wherein the low-profile implantable medical device is a neurostimulator that provides deep brain stimulation for the method of claim 28, as recited by claim 32. No new matter has been added by the new claim.

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CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Applicant does not acquiesce with any of the Examiner's current rejections or characterizations of the prior art, and reserve the right to further address such rejections and/or characterizations.

Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date: July 17, 2008

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